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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,639	01/22/2004	Dmitry E. Protsenko	UCI.PAU.33	5303

23386 7590 06/01/2007

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EXAMINER	
VRETTAKOS, PETER J	
ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,639	PROTSENKO ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5-17-07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-40,46,47 and 49-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-40,46,47 and 49-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The action is non-final.

Claims 35-40, 46-47 and 49-56 are examined below. Claim 35 is the lone independent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-39 and 49-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Eggers et al. (6,557,559).

Eggers et al. discloses in numerous embodiments (see figures 1, 2, 16, 16a, 17) devices for shaping/recontouring cartilage (col. 5:60-67; col. 7:55-60; col. 12:15-20) for use in methods (claims 33, 46, 69) including pressuring/creating stress/mechanically applying force in target tissue with a probe and applying electrical energy to the target tissue (see col. 6:61-67). Eggers also discloses arrayed electrodes/paired conductive elements (58), a power source (28), voltage source (98), a controller including temperature feedback control (28), selector (30 - changes applied voltage level), constant current flow (col. 9:20-25) and control (duration, level, intervals) of the voltage pulses (col. 8:19-33).

With regards to the Applicant's claims:

35. An apparatus of electroforming tissue comprising:

means for creating stress in the tissue (see col. 6:61-67) to temporally define and maintain a predetermined shape of the tissue (the physical presence of the probe may temporally physically displace the tissue while the probe is adjacent the tissue); and

means for causing a current to flow in the tissue (see col. 6:61-67; power source 28, voltage source 98, electrodes 58) while the created stress is present to permanently change (changes resulting from current application) shape of the tissue or material parameters of the tissue without necrosis or ablation (col. 5:60-67; col. 7:55-60; col. 12:15-20).

36. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for causing a direct current (col. 9:20-25) of a predetermined polarity (col. 1:30-35) to flow (power source 28, voltage source 98, electrodes 58) in the tissue to mediate the tissue.

37. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for mechanically applying force (see col. 6:66-67) to the tissue to create external stresses applied to the tissue to temporally define and maintain a predetermined shape (col. 5:60-67; col. 7:55-60; col. 12:15-20) of the tissue.

38. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for changing material parameters (see col. 6:61-67) of the tissue to create internal stresses in the tissue to permanently change its shape (col. 5:60-67; col. 7:55-60; col. 12:15-20) to the predetermined shape.

39. The apparatus of claim 38 where the means for changing material parameters of the tissue comprises means for (power source 28, voltage source 98, electrodes 58) causing a direct current (col. 9:20-25) to flow in the tissue.

49. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying voltage pulses (power source 28, voltage source 98, electrodes 58) of the same polarity to form a DC pulse train (control of pulses disclosed in col. 8:19-33; element 30).

50. The apparatus of claim 49 where the means for applying a voltage of predetermined polarity (power source 28, voltage source 98, electrodes 58) to obtain a predetermined bioeffect comprises means for applying a first sequence of voltage pulses of the same polarity and means for applying a second sequence of voltage pulses of the opposite polarity to form a complex DC pulse train (control of pulses disclosed in col. 8:19-33; element 30).

51. The apparatus of claim 50 where the means for applying a first sequence and means for applying a second sequence of voltage pulses provide a net charge cancellation when integrated over an application time (control of pulses disclosed in col. 8:19-33; element 30).

52. The apparatus of claim 49 where the means for applying a voltage of predetermined polarity to obtain a predetermined bioeffect comprises means for flowing direct current from a positive electrode to obtain tissue compression in the proximity of the positive electrode. The patent inherently includes tissue compression at the positive electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

53. The apparatus of claim 49 where the means for applying a voltage of predetermined polarity to obtain a predetermined bioeffect comprises means for flowing direct current from a negative electrode to obtain tissue lengthening in the proximity of the negative electrode. The patent inherently includes tissue lengthening at the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

54. The apparatus of claim 35 where the means for creating stress in the tissue comprises creating means for (col. 6:61-67) tension, compression, shear or combinations thereof in the tissue. The patent inherently includes tissue lengthening at

the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

55. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying a DC voltage (power source 28, voltage source 98) for a predetermined application time across two paired conductive elements (electrodes 58) in contact with the tissue.

56. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined application time across two paired conductive elements comprises means for (10) placing a solid conductive element (electrodes 58) in contact with the tissue, including solid conductive elements composed of metals or conductive polymers (col. 13:64-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (6,557,559) in view of Balbierz (6,770,070).

Eggers is silent concerning monitoring stresses (although Eggers does disclose monitoring temperature).

Balbierz discloses an analogous arrayed (Balbierz claim 34) electrode catheter with feedback control. Turning the Applicant's claims Balbierz also discloses/makes obvious:

40. The apparatus of claim 35 further means for comprising monitoring (324 in figure 27; see col. 18:7-27) the stresses in the tissue and means for controlling (338 in figure 27, 350,329,346) the current flowing in the tissue according to the stresses therein.

46. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color of the tissue as caused by a chemical dye (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) disposed therein.

47. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) of the tissue as caused by electroplating a material thereon.

Moving to Balbierz disclosure in col. 22:44-60:

"Referring now to FIGS. 27 and 28, a feedback control system 329 can be connected to energy source 320, sensors 324 and energy delivery devices 314 and 316. ***Feedback control system 329 receives temperature or impedance data from sensors 324*** and the amount of electromagnetic energy received by energy delivery devices 314 and 316 is modified from an initial setting of ablation energy output, ablation time, temperature, and current density (the "Four Parameters"). Feedback control system 329

can automatically change any of the Four Parameters. Feedback control system 329 can detect impedance or temperature and change any of the Four Parameters. Feedback control system 329 can include a multiplexer to multiplex different antennas, a temperature detection circuit that provides a control signal representative of temperature or impedance detected at one or more sensors 324. A microprocessor can be connected to the temperature control circuit."

Earlier in Balbierz (col. 18:7-27), more types of sensors including those making obvious the Applicant's claims are disclosed (implicitly used in a feedback control configuration):

"Sensor 22 can be of conventional design, including but not limited to **thermal sensors, acoutiscal sensors, optical sensors, pH sensors, gas sensors, flow sensors positional sensors and pressure/force sensors**. Thermal sensors can include thermistors, thermocouples, resistive wires, optical sensors and the like. A suitable thermal sensor 22 includes a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. Acoustical sensors can include ultrasound sensors including piezoelectric sensors which can be configured in an array. Pressure and force sensors can include **strain gauge sensors** including silicon-based strain gauges. Optical sensors can include photomultipliers and micro-machined optical fibers. Gas sensors can include O2 sensors such as Clark electrodes, CO2 sensors and other electrochemical based sensors known in the art. Flow/velocity sensors can include ultrasound sensors, electromagnetic sensors and aneometric sensors which can be configured to detect both liquid and gaseous flows. Positional sensors can include LVDT's, and Hall effect sensors. Other sensors which can be employed impedance sensors, antibody-based sensors, biosensors (e.g. glucose) and chemical sensors. In various embodiments one sensor can be configured to detect multiple parameters or one or more sensors can be coupled together."

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Eggers in view of Balbierz by including as a design expedient monitoring of stress in the targeted tissue. The motivation would be to provide an alternate to Eggers' temperature feedback control as implied as beneficial by the fact that Balbierz provides an alternate to temperature feedback control (ex. impedance feedback control) in the above provided Balbierz disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
May 24, 2007

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Art Unit 3739